EASYSPRAY

PRESSURE REGULATOR

INSTRUCTIONS FOR USE

Advancing BioSurgery

Baxter

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1. DESCRIPTION

The EASYSPRAY Pressure Regulator controls and releases pressurized gas provided by a propellant gas source. The EASYSPRAY device is to be used only with spray sets specified for use with this pressure regulator.

Only qualified operating room personnel should operate the device, having first read this manual carefully.

1.1 CONTENTS OF CARTON

1 EASYSPRAY Pressure Regulator
1 Instruction manual

1.2 ACCESSORIES

In addition to the EASYSPRAY device, a spray set device is required for the spray application of surgical sealants. Only spray sets designated for use with the EASYSPRAY device should be used. The spray sets consist of a sterile spray tip attached to dual-lumen tubing for gas delivery and activation of the pressure-sensitive on/off mechanism.

Contact your Baxter representative to obtain suitable spray sets.

1.3 SYMBOLS

Symbol	Explanation
	Classification of Device: Equipment provides a degree of protection against electrical shock
	Attention, See Instructions Manual
	'On' position
	'Off' position
	Low Battery Indicator
	DO NOT connect to an oxygen source

2. WARNINGS AND PRECAUTIONS

- ***CAUTION:*** Pressurized gas supply must be between 3.5 and 7 bar.
- ***CAUTION:*** DO NOT connect to an oxygen source. Failure to follow these instructions can lead to explosion, which could result in serious injury or death.
- Prior to operation make sure that the pressure range of the device is adjusted to the range specified in the appropriate spray set instructions for use (See 4.1 FIRST-TIME USE).
- ***CAUTION:*** Any application of pressurized gas may be associated with a potential risk of air embolism, tissue rupture or gas entrapment with compression, which may be life threatening. Be sure to take appropriate measures to address these risks by observing the recommended minimum spraying distance and maximum pressure provided in the appropriate spray set instructions for use.
- ***CAUTION:*** Spraying into enclosed body cavities requires appropriate safety measures to make sure that the above mentioned risks will be avoided.

ATTENTION:

- DO NOT throw or drop the device!
- Do not use the device in the case of visible damage caused by improper handling. Return damaged devices to Baxter for repair.

3. STORAGE

- Storage and Transport Conditions: Temperature -10° to 45°C, 60% relative air humidity.
- Protect from heat, dust, humidity, frost and direct sunlight.

If the device is not used on a regular basis, observe the following:

- Prior to each re-use, perform a functional test (See 4.1 FIRST-TIME USE).
- Connect the device to the pressurized gas supply and vent at the maximum pressure by repeatedly closing the sensing line luer connector.

4. OPERATION

4.1 FIRST-TIME USE

After removing the device from the package, it is recommended to keep the carton for potential maintenance or repair. Check the device visually for any mechanical damage that could impair operation.

Open the battery compartment with the aid of a coin or screwdriver and insert a standard 9 Volt battery. NOTE: Do not use rechargeable batteries.

Since operating rooms are equipped with various types of fittings for pressurized gas,

the connection tube of the EASYSPRAY device is supplied without fittings. The appropriate fitting must be mounted to the end of the supply line by technical service personnel.

Prior to first time use, the protective caps have to be removed from the gas connections.

The recommended pressurized gas source is compressed air or nitrogen.

CAUTION: Pressurized gas supply must be between 3.5 and 7 bar.

4.2 PREPARING FOR OPERATION

The device should be visually inspected for any mechanical damage that could impair the function at regular intervals.

If the low-battery indicator light is illuminated, change battery immediately.

If the device is no longer safe in function and/or operation, discontinue use and return it to Baxter in accordance with Section 7 (RETURN OF DEVICES).

4.3 OPERATION

- The clamp on the back side of the EASYSPRAY device allows the device to be mounted onto an IV-pole or a bed-rail. Firmly set screws to assure stable connection to either the IV-pole or bed-rail.
- Connect the supply line to pressurized gas outlet in the OR (compressed air or nitrogen).

CAUTION: Pressurized gas supply must be between 3.5 and 7 bar.

NOTE: Follow instructions for use for surgical sealant and spray device preparation.

- Connect the clear sterile filter of the spray set pressure line to the male luer connector on the EASYSPRAY device. Connect the blue filter of the spray set sensing line to the blue marked female luer connector on the EASYSPRAY device.
- Turn the switch on the front side of the EASYSPRAY device to the ON-position (I).
- Adjust the pressure on the EASYSPRAY device according to the specifications in the spray set instructions for use by turning the regulator knob in the appropriate direction.
- To activate the flow of gas, cover the sensing line outlet (the hole on the spray set clip) as described in the spray set instructions for use.
- The quantity of product applied is controlled by the product application system but not by the gas released.
- When spraying of sealant has been completed or the EASYSPRAY device is no longer in use, turn the switch on the front side to the OFF-position (O).

CAUTION: For the recommended spraying distance, gas pressure and application details read the spray set instructions for use carefully.

5. CLEANING / MAINTENANCE

5.1 CLEANING

The EASYSPRAY housing can be cleaned with standard operating room disinfectants.

In order for the device to operate safely and in accordance with the intended use, the device must be cleaned following use and maintained free of dirt and other debris.

5.2 PERIODIC TECHNICAL-SAFETY INSPECTIONS (OUTLINE)

The following technical safety inspection has to be performed periodically (at least once a year) by the hospital technical service:

Pressurized Gas Supply Line:

1. Disconnect the device from the gas supply line connector.
2. Inspect the supply line for damage (breaks, leaks and wear)
3. Check the gas connector

Particle Filter:

1. Disconnect the device from the gas supply.
2. Dismount the filter housing (use wrench size SW 32mm if necessary).
3. Replace the filter element, inspect sealing rings for damage and replace if necessary. (Filter and sealing ring set can be obtained from your Baxter representative.)
4. Mount the filter housing.

Labels:

Inspect all labels and stickers for legibility and completeness.

Mechanical Condition:

The external mechanical condition must allow safe operation and function of the appliance. Carefully check for any damage to the Luer-Lock connections and ensure they are tightly fastened.

Pressure Gauge:

Inspection of the pressure gauge:

1. Connect the EASYSPRAY device to the propellant gas supply.
2. Attach a calibration manometer (calibrator) with measuring range of at least 4 bar to the pressure line connector.
3. Switch the On/Off switch into the On position (I).
4. Close the sensing line connector.
5. Turn the pressure control knob to set a pressure of 1 bar on the calibrator.
6. The pressure displayed on the pressure gauge must be between 0.9 and 1.1 bar
7. Turn the pressure control knob to set a pressure of 2 bar on the calibrator.
8. The pressure displayed on the pressure gauge must be between 1.9 and 2.1 bar.
9. Turn the pressure control knob to set a pressure of 3 bar on the calibrator.
10. The pressure displayed on the pressure gauge must be between 2.9 and 3.1 bar.

Overpressure Shut-Down:

Inspection of the overpressure shut-down mechanism:

1. Connect the EASYSPRAY device to the pressurized gas supply.
2. Switch the On/Off switch into the On position (I).
3. Use the pressure control knob to set a pressure of approx. 2.8 bar.
4. Attach a calibration manometer (calibrator) with measuring range of at least 4 bar to the pressure line connector.
5. Dismount the pressure regulator knob with the aid of an Allen wrench (2.5 mm).
6. Remove the retaining washer.
7. Mount the pressure control knob.
8. Close/Cover the sensing line connector to start gas flow through the EASYSPRAY device and set the output pressure to 2.8 bar.
9. Check the function of the EASYSPRAY device by starting it repeatedly, i.e., covering and uncovering the sensing line connector.
10. Using the pressure regulator increase the output pressure by 0.1 bar.
11. Repeat points 9 and 10 until gas flow through the device is interrupted (shut-down pressure has been reached).
12. The shut-down pressure must be between 3.1 bar and 3.7 bar (3.4 +/- 0.3 bar).
13. Switch the On/Off switch to Off (O).
14. Dismount the pressure control knob.
15. Reinstall the retaining washer.
16. Mount the pressure control knob.

Battery Inspection:

1. Open the battery compartment with the aid of a coin or screwdriver and remove the battery from drawer.
2. Check the battery compartment and the drawer for contaminants.
3. Check the contact springs for corrosion.
4. Test the battery voltage (using a battery tester if necessary) or dispose of the battery in accordance with the local regulations.
5. Re-insert the tested or new battery into the drawer and test the device for function.

6. TERMS OF GUARANTEE

The manufacturer guarantees that all defects in material and fabrication occurring within 2 years after the date of sale are repaired free of charge.

This guarantee can only be claimed under the following conditions:

- Inform Baxter immediately of malfunction. Please provide the serial number of the device when reporting.
- Observe all instructions regarding storage or return of the device.
- Present a legible copy of the invoice for the device in question, which clearly shows the date of sale.
- Describe as exactly as possible the suspected defects or malfunctions by the user.

ATTENTION: The guarantee will not be applicable, if directions for maintenance, cleaning, and inspection in accordance with the instruction manual have not been followed.

The manufacturer and the supplier of the device deny liability, if:

- The device is not used in accordance with the instruction manual.
- The defect was not caused by the manufacturer or persons and service companies authorized by the same.

7. RETURN OF DEVICES

Reasons for return:

1. Results of the first-time use tests are unsatisfactory/unsafe
2. Defective device

Please contact Baxter customer service to obtain a RETURN AUTHORIZATION (RA) NUMBER prior to returning. Product returns will not be accepted without a Return Authorization number.

When returning a device, clean it carefully and pack it in the original package. If the original package is no longer available, the device has to be packaged in a manner corresponding to the original package, i.e. individually and shockproof.

8. WASTE DISPOSAL OF PRODUCT

- Do not dispose product (device) as unsorted municipal waste.
- Collect product (device) separately.
- Use collection and return systems available to you.

9. TECHNICAL DATA

• Outer dimensions	L 155 mm x W 240 mm x H 160 mm
• Gas supply line	L 5 m x 6 mm
• Weight	1.8 kg
• Pressurized gas supply	3.5 – 7 bar
• Maximum pressure	3.0 +/- 0.2 bar
• Admissible pressurized gases	Compressed air or nitrogen
• Operating conditions	Temperature: 10°-40°C, 30-75% relative air humidity, avoid shocks and vibrations.

10. MANUFACTURER AND DISTRIBUTOR

Distributed in the USA by:
Baxter Healthcare Corporation
Westlake Village, CA 91362
1-800-423-2090

US: Rx Only

11. ELECTROMAGNETIC COMPATIBILITY INFORMATION

according to IEC 60601-1-2:2001:

The EasySpray Pressure Regulator, as well as all medical electrical equipment, needs special precautions regarding EMC (electromagnetic compatibility) and needs to be installed and put into service according to the following information.

- Because the intensity of electromagnetic energy is greatest near the source of a transmitting antenna, portable and mobile RF communications equipment can affect medical electrical equipment.

The EasySpray Pressure Regulator has been designed to withstand the effects of EMI (electromagnetic interference) and meets the most current EMC standards that apply to the instrument. However, extremely high levels of electromagnetic energy (above the levels of IEC 60601-1-2) may still produce interference.

To reduce the risk of EMI, follow these recommendations:

- Do not turn on or use hand-held personal communications devices, such as mobile two-way radios or cellular phones, near the instrument. If these devices need to be used, follow the "recommended separation distance" as shown in the following tables.
- In the case of unexplained EMI, consider the locations of nearby transmitters, such as radio or TV stations. You may have to move the instrument or place shield material between the transmitter and the instrument.
- Be aware that modifying the instrument or adding accessories or components, not specifically authorized by Baxter, may make the instrument more susceptible to interference from radio waves.

WARNING: When servicing the instrument, use only replacement components, cables and accessories authorized by Baxter and be sure to replace all shields, covers, screws, and gaskets in their exact locations as described in the service manual. Failure to do so may result in increased emissions or decreased immunity of the instrument.

WARNING: The EasySpray Pressure Regulator should not be used adjacent to, or stacked with, other medical electrical equipment. However, if it is necessary to use the instrument close to other equipment, the instrument should be observed to verify normal operation in the configuration in which it is intended to be used.

Table 201 - Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The EasySpray Pressure Regulator is intended for use in the electromagnetic environment specified below. The user of the EasySpray Pressure Regulator should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The EasySpray Pressure Regulator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The EasySpray Pressure Regulator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Table 202 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The EasySpray Pressure Regulator is intended for use in the electromagnetic environment specified below. The user of the EasySpray Pressure Regulator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 204 - Guidance and Manufacturer's Declaration - Electromagnetic Immunity – For Equipment and Systems that are Not Life-Supporting

The EasySpray Pressure Regulator is intended for use in the electromagnetic environment specified below. The user of the EasySpray Pressure Regulator should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, Am and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EasySpray Pressure Regulator is used exceeds the applicable RF compliance level above, the EasySpray Pressure Regulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EasySpray Pressure Regulator.

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